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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BUCKLEY, AUDREA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,017	Applicant(s) ANDERSEN, THORKILD	
	Examiner AUDREA J. BUCKLEY	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, and 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/11/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Acknowledgement is made of Applicants' amendments to the claims filed 12/11/2009. Support is found in the specification for the amendments to the claims. Applicants' amendments to the specification filed 12/11/2009 are acknowledged and entered into the record.

Claims 1, 2, 8, 9, and 11-21 are now pending and considered herein.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/11/2009 was filed after the mailing date of the application on 9/18/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Withdrawn Claim Rejections

The rejection of claims 1 and 8 under 35 USC 102(b) as anticipated by Vanderlaan et al. (US 2002/0197299) is withdrawn in light of Applicants' amendments to the claims filed 12/11/2009.

The rejection of claims 1, 2, 8, and 9 under 35 USC 103(a) as being unpatentable over Vanderlaan et al. is withdrawn in light of Applicants' amendments to the claims filed 12/11/2009.

New Grounds of Rejection As Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 16, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite because the metes and bounds of the term “in an amount effective to provide at least an antimicrobial effect” are unclear as the term relates to the quantity of titanium oxide photocatalyst. It is noted that page 11 of the specification defines the quantity of silver particles needed for the desired antimicrobial effect. The instant specification does not define in any limiting way the “amount effective” as it relates to titanium oxide, therefore it is unclear to the skilled artisan as to what would infringe the rejected claims. The “amount effective” alludes to a quantity but no standard for ascertaining the requisite degree of consequential "antimicrobial effect" has been provided. As such, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate clarification or correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 8, 9, and 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderlaan et al. (US 2002/0197299 A1) in view of Schlitzer (WO 95/34327, filed May 1995, see IDS 11/15/2006) and Yadav et al. (US 2005/0008861, filed Dec. 2003).

Regarding claims 1, 8, and 16, Vanderlaan et al. teach antimicrobial contact lenses and containers which comprise nanosize silver powder as an antibacterial agent. Further regarding claims 11, 17, and 21, the containers are made of thermoplastic polymeric material structured from a mold (page 2, column 2, [0016]) and may be adapted to define a space in which to hold a lens (page 2, column 2, [0014]). It is specified that the lens container, the lens basket, or the top of the lens container may contain activated silver (page 3, column 1, [0018]) and the method for implementing the silver active agent into the polymeric molded article which is the antimicrobial lens container or its components is the same method as disclosed for implementing the silver active agent into the antimicrobial lenses.

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Vanderlaan does not teach that the antibacterial agent is implemented as a coating.

However, Schlitzer teaches a method for storing contact lenses using a lens case having a bactericidal coating (see abstract, in particular). Particularly, Example 1 teaches that the wells of a thermoplastic contact lens case being silver coated and filled with liquids demonstrated improved microbial control when compared with the non-coated wells (see page 3, line 27 – page 4, line 14).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antimicrobial coating taught by Schlitzer into the contact lens containers as taught by Vanderlaan et al. The skilled artisan would have been motivated to do so in order to continue the improved microbial control upon the added silver coating as taught by Schlitzer in contact lens case applications.

Although Vanderlaan teaches the presence of silver nanoparticles, these nanoparticles are not expressly present as a coating. Similarly, Schlitzer does not expressly teach that the silver active antimicrobial agent is in the form of nanoparticles. Regarding claim 2 and further regarding claims 9, 12-15, and 18-20, neither of these references limits the particle size or the concentration of the antimicrobial silver active agent when this active agent is implemented into a coating.

However, Yadav et al. teach silver comprising nanoparticles and related nanotechnology wherein these nanoparticles are utilized as coatings for antimicrobial formulations (see abstract, in particular; see also, [0172]). Yadav et

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al. teach an embodiment of the invention in which nanoscale or submicron powders are incorporated into plastics used for coatings by (a) preparing nanoscale or submicron powders comprising silver, (b) providing a film of one or more plastics, and (c) coating the nanoscale or submicron powders on the film of the plastic. Further, in certain embodiments, the grain size of the coating is less than 200 nm and in other embodiments less than 75 nm and in certain embodiments less than 25 nanometers. In certain embodiments, the nanoparticles may be applied on the surface of a plastic (see page 6, paragraph [0071]). In further analysis of silver nanoparticles in consumer applications, silver comprising nanoparticles may be added in small concentrations into contact lenses polymers and to lens cleaning formulations to increase comfort and to provide strong anti-microbial action (in certain embodiments below 10% by weight, in certain embodiments below 1%, and in certain embodiments below 0.1%) (see page 10, paragraph [0140]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate small quantities of silver nanoparticles in ranges overlapping with those taught by Yadav et al. with respect to contact lens applications into the contact lens container applications disclosed by Vanderlaan et al. and Schlitzer. One would have been motivated to do so to provide increased eye/lens comfort and to provide optimally strong anti-microbial action in accordance with the disclosure of Yadav et al.

Response to Arguments

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Applicants' arguments presented 12/11/2009 have been fully considered but are moot in light of amendment. As noted above, all rejections previously presented but not re-iterated herein are withdrawn. Applicants' positions against cited references are summarized and responded to as follows.

Applicants traverse the rejection of claims 1 and 8 under 35 USC 102(b) as anticipated by Vanderlaan et al. since Vanderlaan's activated silver does not describe a silver coating on the container or insert. This position has been fully considered but is moot in light of amendment.

Applicants traverse the rejection of claims 1, 2, 8, and 9 under 35 USC 103(a) as being unpatentable over Vanderlaan et al. since the claimed invention provides an antimicrobial container/insert while the cited reference provides a bacteriostatic container/insert. Applicants further state that the claimed invention is easier to produce and has a greater quantity of effective silver despite the lesser quantity of total silver, when compared with the prior art cited. In reply, it is the Examiner's position that Applicant has not provided any objective evidence to demonstrate the asserted unexpected results of the instant invention. A showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997). See also MPEP 716.01 (c). Therefore, Applicant's position has been fully considered but is moot in light of amendment.

Conclusion

No claims are found allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611